

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE


INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	1	of	10	Attorney Docket Number	224491

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date if appropriate MM-DD-YYYY
		Document Number	Kind Code			
JER	IY	US- 5,003,097		03-26-1991	Beaucage et al.	
JER	IZ	US- 5,264,423		11-23-1993	Cohen et al.	
JER	JA	US- 5,276,019		01-04-1994	Cohen et al.	
JER	JB	US- 5,286,717		02-15-1994	Cohen et al.	
JER	JC	US- 5,965,519		10-12-1999	Yatvin et al.	
JER	JD	US- 6,126,965		10-03-2000	Kasid et al.	
JER	JE	US- 6,183,958		02-06-2001	Stanton, Jr.	
JER	JF	US- 6,291,175		09-18-2001	Sévigny et al.	
JER	JG	US- 6,333,314		12-25-2001	Kasid et al.	
JER	JH	US- 6,368,797		04-09-2002	Schappert	
JER	JI	US- 6,395,481		05-28-2002	Di Rienzo et al.	
JER	JJ	US- 6,475,736		11-05-2002	Stanton, Jr. et al.	
JER	JK	US- 6,559,129		05-06-2003	Kasid et al.	
JER	JL	US- 6,500,650		12-31-2002	Stanton, Jr. et al.	
JER	JM	US- 6,537,759		03-25-2003	Stanton, Jr. et al.	
JER	JN	US- 6,573,049		06-03-2003	Schappert	
JER	JO	US- 6,582,923		06-24-2003	Stanton, Jr. et al.	
JER	JP	US- 6,610,492		08-26-2003	Stanton, Jr. et al.	
JER	JQ	US- 6,664,062		12-16-2003	Stanton, Jr.	
JER	JR	US- 2002/0150943	A1	10-17-2002	Stanton, Jr. et al.	
JER	JS	US- 2003/0073123	A1	04-17-2003	Shen et al.	
JER	JT	US- 2003/0215489	A1	11-20-2003	Kasid et al.	
JER	JU	US- 2003/0219476	A1	11-27-2003	Ahmad et al.	
JER	JV	US- 2003/0225023	A1	12-04-2003	Kasid et al.	
JER	JW	US- 2003/0228317	A1	12-11-2003	Gokhale et al.	

- * A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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Examiner Signature	/Jeffrey Russel/	Date Considered	05/02/2006
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JER	JX	US- 2003/0229040	A1	12-11-2003	Kasid et al.	
JER	JY	US- 2004/0005603	A1	01-08-2004	Kasid et al.	
JER	JZ	US- 2004/0082771	A1	04-29-2004	Kasid et al.	
JER	KA	US- 2004/0106571	A1	06-03-2004	Kasid et al.	
JER	KB	US- 2004/0115714	A1	06-17-2004	Kasid et al.	
JER	KC	US- 2004/0248218	A1	12-09-2004	Kasid et al.	
JER	KD	US- 2005/0002918	A1	01-06-2005	Strauss et al.	
JER	KE	US- 2005/0019387	A1	01-27-2005	Rahman et al.	
JER	KF	US- 2005/0148528	A1	07-07-2005	Gately	
JER	KG	US- 2005/0153297	A1	07-14-2005	Ahmad et al.	
JER	KH	US- 2005/0181037	A1	08-18-2005	Ahmad et al.	
JER	KI	US- 2005/0202074	A1	09-15-2005	Rahman	
JER	KJ	US- 2005/0238706	A1	10-27-2005	Ahmad et al.	
JER	KK	US- 2005/0249795	A1	11-10-2005	Zhang et al.	
JER	KL	US- 2005/0266068	A1	12-01-2005	Ahmad et al.	
JER	KM	US- 2005/0277611	A1	12-15-2005	Ahmad et al.	
JER	KN	US- 09/354,109			Kasid et al.	07-15-1999
JER	KO	US- 09/930,283			Kasid et al.	08-16-2001
JER	KP	US- 10/056,210			Kasid et al.	01-28-2002
JER	KQ	US- 10/239,598			Rahman	10-25-2000
JER	KR	US- 10/680,313			Kasid et al.	10-06-2003
JER	KS	US- 60/041,192			Kasid et al.	03-21-1997
JER	KT	US- 60/241,069			Rahman et al.	10-16-2000
JER	KU	US- 60/264,062			Kumar et al.	01-26-2001
JER	KV	US- 60/281,779			Kasid et al.	04-06-2001

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
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		Document Number	Kind Code			
JER	KW	US- 60/281,780			Kasid et al.	04-06-2001
JER	KX	US- 60/281,785			Kasid	04-06-2001
JER	KY	US- 60/281,796			Kasid et al.	04-06-2001
JER	KZ	US- 60/314,959			Rahman et al.	08-24-2001
JER	LA	US- 60/332,477			Strauss et al.	11-09-2001
JER	LB	US- 60/371,116			Kasid et al.	04-10-2002
JER	LC	US- 60/371,126			Kasid et al.	04-10-2002
JER	LD	US- 60/382,031			Gokhale et al.	05-22-2002
JER	LE	US- 60/382,411			Gately	05-20-2002
JER	LF	US- 60/383,340			Ahmad et al.	05-24-2002
JER	LG	US- 60/384,222			Ahmad et al.	05-29-2002
JER	LH	US- 60/405,378			Zhang et al.	08-23-2002
JER	LI	US- 60/419,277			Ahmad et al.	10-16-2002
JER	LJ	US- 60/429,285			Ahmad et al.	11-26-2002
JER	LK	US- 60/438,659			Ahmad et al.	01-07-2003
JER	LL	US- 60/444,958			Zhang et al.	02-03-2003
JER	LM	US- 60/446,895			Bhamidipati et al.	02-11-2003
JER	LN	US- 60/457,898			Gately et al.	03-26-2003
JER	LO	US- 60/467,331			Ahmad et al.	05-02-2003
JER	LP	US- 60/472,664			Jamil et al.	05-22-2003
JER	LQ	US- 60/480,669			Jamil et al.	06-23-2003
JER	LR	US- 60/495,260			Jamil et al.	08-13-2003
JER	LS	US- 60/514,658			Ahmad et al.	10-27-2003

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		Office	Number	Kind Code				
JER	LT	EP	0 288 255	A2	10-26-1988	The Japanese Research and Development Association for Bioreactor System		<input type="checkbox"/>
JER	LU	EP	1 352 970	A1	10-15-2003	Nagoya Industrial Science Research Institute		<input type="checkbox"/>
JER	LV	SU	629927	A	10-30-1978	Bacterial Preparation Works		<input checked="" type="checkbox"/>
JER	LW	SU	1186212	A	10-23-1985	Inst. Biologicheskoy Med. Khimii		<input checked="" type="checkbox"/>
JER	LY	WO	98/43095	A	10-01-1998	Georgetown Univ.		<input type="checkbox"/>
JER	LY	WO	00/01366	A	01-13-2000	NeoPharm, Inc.		<input type="checkbox"/>
JER	MZ	WO	00/52210	A	09-08-2000	Variagenics, Inc.		<input type="checkbox"/>
JER	MA	WO	01/53460	A	07-26-2001	Variagenics, Inc.		<input type="checkbox"/>
JER	MB	WO	01/70220	A	09-27-2001	NeoPharm, Inc.		<input type="checkbox"/>
JER	MC	WO	02/32400	A	04-25-2002	NeoPharm, Inc.		<input type="checkbox"/>
JER	MD	WO	02/059337	A	08-01-2002	Georgetown Univ. School of Medicine		<input type="checkbox"/>
JER	ME	WO	02/081639	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MF	WO	02/081640	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MG	WO	02/081641	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MH	WO	02/081642	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
JER	MI	WO	02/088714	A	11-07-2002	McGill University		<input type="checkbox"/>
JER	MJ	WO	03/013536	A	02-20-2003	Epidauros Biotechnologie AG		<input type="checkbox"/>

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		Office	Number	Kind Code				
JER	MK	WO	03/013537	A	02-20-2003	Epidauros Biotechnologie AG		<input type="checkbox"/>
JER	ML	WO	03/018018	A	03-06-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MM	WO	03/039600	A	05-15-2003	NeoPharm, Inc.		<input type="checkbox"/>
JER	MN	WO	03/070221	A	08-28-2003	Georgetown Univ.		<input type="checkbox"/>
JER	MO	WO	03/099213	A	12-04-2003	NeoPharm, Inc.		<input type="checkbox"/>
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JER	MQ	WO	03/102011	A	12-11-2003	NeoPharm, Inc.		<input type="checkbox"/>
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JER	MS	WO	2004/035523	A	04-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MT	WO	2004/039817	A	05-13-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MU	WO	2004/062569	A	07-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MV	WO	2004/069224	A	08-19-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MW	WO	2004/071466	A	08-26-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MX	WO	2004/087758	A	10-14-2004	NeoPharm, Inc.		<input type="checkbox"/>
JER	MY	WO	2005/000266	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	MZ	WO	2005/000318	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	NA	WO	2005/042028	A	05-12-2005	NeoPharm, Inc.		<input type="checkbox"/>
JER	NB	WO	2005/067632	A	07-28-2005	NeoPharm, Inc.		<input type="checkbox"/>


OTHER - NON PATENT LITERATURE DOCUMENTS			
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JER	NC	Office Action mailed December 30, 2005, in U.S. Patent Application No. 10/424,258.	<input type="checkbox"/>
JER	ND	ANDO et al., "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," <i>Ann. Oncol.</i> , 9, 845-847 (1998).	<input type="checkbox"/>

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JER	NE	ANDO et al., "Polymorphisms of UDP-glucuronosyltransferase gene and irinotecan toxicity: a pharmacogenetic analysis," <i>Cancer Res.</i> 60, 6921-6926 (2000).	<input type="checkbox"/>
JER	NF	BOSMA et al., "Bilirubin UDP-glucuronosyltransferase 1 is the only relevant bilirubin glucuronidating isoform in man," <i>J. Biol. Chem.</i> 269, 17960-17964 (1994).	<input type="checkbox"/>
JER	NG	BOSMA et al., "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome," <i>New Engl. J. Med.</i> 333, 1171-1175 (1995).	<input type="checkbox"/>
JER	NH	CERSOSIMO et al., "A new antineoplastic agent for the management of colorectal cancer," <i>Ann. Pharmacother.</i> 32:1324-1333, (1998)	<input type="checkbox"/>
JER	NI	DRUMMOND et al., "Optimizing Liposomes for Delivery of Chemotherapeutic Agents to Solid Tumors," <i>Pharmacol. Rev.</i> 51, 691-743 (1999).	<input type="checkbox"/>
JER	NJ	FISHMAN et al., "Phase I study of Liposomal SN-38 (LE-SN38) in Patients With Advanced Cancer: Pharmacogenomics and Pharmacokinetics," <i>AARC-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics</i> (Boston, MA), Abstract B250 (November 2003).	<input type="checkbox"/>
JER	NK	FISHMAN et al., "Phase I study of liposome encapsulated mitoxantrone (LEM) in patients with advanced cancers," <i>Ann. Oncol.</i> 13 (Suppl. 5), 23 (2002).	<input type="checkbox"/>
JER	NL	GILBERT et al., "Phase I study of 9-nitrocamptothecin (9-NC) liposome aerosol for the treatment of primary and metastatic cancer to the lungs: effect of dose escalation on bronchoalveolar lavage (BAL) and plasma drug levels," <i>Proc. Am. Assoc. Cancer Res.</i> , 43, 430 (Abstract 2138) (2002).	<input type="checkbox"/>
JER	NM	GUPTA et al., "Metabolic fate of irinotecan in humans: correlation of glucuronidation with diarrhea," <i>Cancer Res.</i> 54, 3723-3725 (1994).	<input type="checkbox"/>
JER	NN	GUTBERLET et al., "Cardiolipin, α -D-glucopyranosyl, and L-lysylcardiolipin from Gram-positive bacteria: FAB MS, monifilm and X-ray powder diffraction studies," <i>Biochim. Biophys. Acta</i> , 463, 307-322 (2000).	<input type="checkbox"/>
JER	NO	HECHT, "Gastrointestinal toxicity of irinotecan," <i>Oncology</i> 12, 72-78 (1998).	<input type="checkbox"/>

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JER	NP	HSIANG et al., "Arrest of replication forks by drug-stabilized topoisomerase I-DNA cleavable complexes as a mechanism of cell killing by camptothecin," <i>Cancer Res.</i> 49, 5077-5082 (1989).	<input type="checkbox"/>	
JER	NQ	HSIANG et al., "Camptothecin induces protein-linked DNA breaks via mammalian DNA topoisomerase I," <i>J. Biol. Chem.</i> 260, 14873-14878 (1985).	<input type="checkbox"/>	
JER	NR	INNOCENTI et al., "UGT1A1 *28 polymorphism is a predictor of neutropenia in irinotecan chemotherapy," <i>Proc. Am. Soc. Clin. Oncol.</i> , 22, 124 (Abstract 495) (2003).	<input type="checkbox"/>	
JER	NS	IYER et al., "Genetic predisposition to the metabolism of irinotecan (CPT-11). Role of uridine diphosphate glucuronosyltransferase isoform 1A1 in the glucuronidation of its active metabolite (SN-38) in human liver microsomes," <i>J Clin Invest</i> 101:847-854, (1998)	<input type="checkbox"/>	
JER	NT	IYER et al. "Phenotype-genotype correlation of in vitro SN-38 (active metabolite of irinotecan) and bilirubin glucuronidation in human liver tissue with UGT1 A1 promoter polymorphism," <i>Clin. Pharmacol. Ther.</i> , 65, 576-582 (1999).	<input type="checkbox"/>	
JER	NU	IYER et al., "UGT1A1 *28 polymorphism as a determinant of irinotecan disposition and toxicity," <i>Pharmacogenetics</i> , 2, 43-47 (2002).	<input type="checkbox"/>	
JER	NV	KEHRER et al., "Factors involved in prolongation of the terminal disposition phase of SN-38: clinical and experimental studies," <i>Clin. Cancer Res.</i> , 6, 3451-3458 (2000).	<input type="checkbox"/>	
JER	NW	KNIGHT et al., "Anticancer effect of 9-nitrocamptothecin liposome aerosol on human cancer xenografts in nude mice," <i>Cancer Chemother. Pharmacol.</i> , 44, 177-186 (1999).	<input type="checkbox"/>	
JER	NX	KRAUT et al., "Pharmacogenomic and pharmacokinetic assessment of liposome encapsulated SN-38 (LE-SN38) in advanced cancer patients," presented at ASCO (American Society of Clinical Oncology), New Orleans, LA, June 5-8, 2004, Abstract 2501 (June 5, 2004).	<input type="checkbox"/>	

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	8	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided ²	
JER	NY	KUNIMOTO et al., "Antitumor activity of 7-ethyl-10-[4-(1-piperidino)-1-piperidino]carbonyloxy-camptothecin, a novel water soluble derivative of camptothecin, against murine tumors," <i>Cancer Res.</i> 47:5944-5947, (1987)	<input type="checkbox"/>	
JER	NZ	LAMPE et al., "UDP-glucuronosyltransferase (UGT1A1 *28 and UGT1A6*2) polymorphisms in Caucasians and Asians: relationships to serum bilirubin concentrations," <i>Pharmacogenetics</i> , 9, 341-349 (1999).	<input type="checkbox"/>	
JER	OA	LAVELLE et al. "Preclinical evaluation of CPT-1 1 and its active metabolite SN-38," <i>Semin. Oncol.</i> , 23, 11-20 (1996).	<input type="checkbox"/>	
JER	OB	MATHIJSSEN et al., "Impact of body-size measures on irinotecan clearance: alternative dosing recommendations," <i>J. Clin. Oncol.</i> , 20, 81-87 (2002).	<input type="checkbox"/>	
JER	OC	MONAGHAN et al., "Genetic variation in bilirubin UDP-glucuronosyltransferase gene promoter and Gilbert's syndrome," <i>Lancet</i> , 347, 578-581 (1996).	<input type="checkbox"/>	
JER	OD	O'LEARY et al, "Camptothecins: a review of their development and schedules of administration," <i>Eur. J. Cancer.</i> , 34, 1500-1508 (1998).	<input type="checkbox"/>	
JER	OE	OSBORNE, "Nastech licenses RNAi patents to boost tight junctions work," <i>BioWorld Today</i> , 15 (21), 1, 6 (February 3, 2004).	<input type="checkbox"/>	
JER	OF	PFIZER, INC., Package insert for Camptosar® (July 2005).	<input type="checkbox"/>	
JER	OG	PITOT et al, "Phase I dose-finding and pharmacokinetic trial of irinotecan hydrochloride (CPT-11) using a once-every-three-week dosing schedule for patients with advanced solid tumor malignancy," <i>Clin Cancer Res.</i> , 6, 2236-2244 (2000).	<input type="checkbox"/>	
JER	OH	RAINIER et al., "Phase transition characteristics of diphosphatidyl-glycerol (cardiolipin) and stereoisomeric phosphatidylglycerol bilayers: mono- and divalent metal ion effects," <i>Biochim. Biophys. Acta</i> , 558, 187-198 (1979).	<input type="checkbox"/>	
JER	OI	RIVORY et al, "Kinetics of the in vivo interconversion of the carboxylate and lactone forms of irinotecan (CPT-11) and of its metabolite SN-38 in patients," <i>Cancer Res.</i> 54:6330-6333, (1994)	<input type="checkbox"/>	

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JER	OJ	RIVORY et al, "Pharmacokinetic interrelationships of irinotecan (CPT-11) and its three major plasma metabolites in patients enrolled in phase I/II trials," <i>Clin. Cancer Res.</i> , 3, 1261-1266 (1997).	<input type="checkbox"/>	
JER	OK	RIVORY, "Metabolism of CPT-11 impact on activity," <i>Ann. N. Y. Acad. Sci.</i> , 922, 205-215 (2000).	<input type="checkbox"/>	
JER	OL	ROTHENBERG, "Topoisomerase I inhibitors: review and update," <i>Ann. Oncol.</i> 8:837-855, (1997)		
JER	OM	SANGHANI et al., "Carboxylesterases expressed in human colon tumor tissue and their role in CPT-11 hydrolysis," <i>Clin. Cancer Res.</i> , 9 (13), 4983-4991 (October 15, 2003).	<input type="checkbox"/>	
JER	ON	SASAKI et al., "Pharmacological correlation between total drug concentration and lactones of CPT-11 and SN-38 in patients treated with CPT-11," <i>Cancer Res.</i> , 86, 111-116 (1995).	<input type="checkbox"/>	
JER	OO	SCHAEPPi et al., "Toxicity of camptothecin (NSC-100880)," <i>Cancer Chemother. Rep.</i> , 5, 25-36 (1974).	<input type="checkbox"/>	
JER	OP	SLATTER et al., "Pharmacokinetics, metabolism and excretion of irinotecan (CPT-11) following iv infusion of [14C]CPT-11 in cancer patients," <i>Drug Metab. Dispos.</i> , 28, 423-433 (2000).	<input type="checkbox"/>	
JER	OQ	STRASSBURG et al., "Jaundice, genes and promoters," <i>J. Hepatol.</i> , 33, 467-479 (2000).	<input type="checkbox"/>	
JER	OR	TAKIMOTO et al., "The camptothecins," in <i>The camptothecins. Cancer chemotherapy and biotherapy</i> , 2nd ed. (Chabner et al., eds.), Chapter 19, 463-484 (Lippincott-Raven, Philadelphia, PA, 1996).	<input type="checkbox"/>	
JER	OS	TREAT et al., "Phase I trial in advanced malignancies with liposome encapsulated paclitaxel (LEP)," <i>Clin. Cancer Res.</i> , 6, 4492s (2000).	<input type="checkbox"/>	
JER	OT	VANHOEFER et al., "Irinotecan in the treatment of colorectal cancer: clinical overview," <i>J. Clin. Oncol.</i> , 19, 1501-1518 (2001).	<input type="checkbox"/>	

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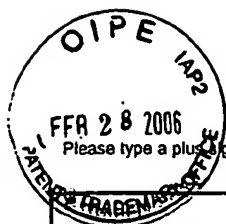
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JER	OU	VAUGHN et al., "A phase I study of a new liposome encapsulated doxorubicin (LED) formulation in advanced malignancies," <i>Proc. Am. Soc. Clin. Oncol.</i> , 19 (23), 1a (Abstract 892) (1999).	<input type="checkbox"/>
JER	OV	WADLER et al., "Recommended guidelines for the treatment of chemotherapy-induced diarrhea," <i>J. Clin. Oncol.</i> , 16, 3169-3178 (1998).	<input type="checkbox"/>
JER	OW	WASSERMAN et al., "Severe CPT-11 toxicity in patients with Gilbert's syndrome: two case reports," <i>Ann. Oncol.</i> , 8, 1049-1051 (1997).	<input type="checkbox"/>

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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		Document Number	Kind Code			

FOREIGN PATENT DOCUMENTS

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/Jeffrey Russel/

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